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Initial experience with the cook formula balloon expandable stent in congenital heart disease

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Abstract: INTRODUCTION: Balloon expandable stents are an integral part in the catheter treatment of congenital heart disease. In the growing child, stents require dilatation to greater diameters over time. The Cook Formula stent is a recent 316 stainless steel open-cell design licensed for peripheral vascular work. **METHODS:** Following extensive ex vivo studies, 112 stents were implanted in 97 children [median age 3.9 (0.01-17.6) years; median weight 13.7 (2.4-62.8) kg] over a 27-month (Oct 2011-Dec 2013) period. **RESULTS:** Bench testing revealed that there was no stent shortening for dilatation to nominal diameter and beyond. The 5 mm stents could be dilated up to 10 mm, and the 10 mm stents to 20 mm. Stents were implanted through 4-7F sheaths or guide catheters over appropriate wires. Stent tracking and delivery was excellent. Twenty-three stents were implanted in the right ventricular outflow tract in Fallot-type lesions, 53 for branch pulmonary artery stenosis (22 post cavopulmonary shunt/Fontan), 14 conduit stenosis, 13 Fontan fenestrations, 3 PDA in hybrid stage I Norwood, 5 in coarctation, and 1 for SVC obstruction. Sixty-one stents (54%) were overdilated. There were no stent fractures. Radial strength was very good, whereas stent conformability was limited. **CONCLUSIONS:** The Cook Formula stent is a premounted balloon-expandable stent that can be significantly overdilated with virtually no shortening allowing for precise placement and minimal protrusion into adjacent vessels. The Formula stent is a very versatile addition to the range of stents for use in the catheter treatment of complex congenital heart disease in children. © 2014 Wiley Periodicals, Inc.

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Initial Experience with the Cook Formula Balloon Expandable Stent in Congenital Heart Disease

Daniel Quandt, MD, Bharat Ramchandani, MD, MRCP, Vinay Bhole, MD, MRCPCH, Gemma Penford, MRCP, Chetan Mehta, MD, MRCP, Rami Dhillon, MRCP, and Oliver Stumper*, MD, PhD

Introduction: Balloon expandable stents are an integral part in the catheter treatment of congenital heart disease. In the growing child, stents require dilatation to greater diameters over time. The Cook Formula stent is a recent 316 stainless steel open-cell design licensed for peripheral vascular work. **Methods:** Following extensive ex vivo studies, 112 stents were implanted in 97 children [median age 3.9 (0.01–17.6) years; median weight 13.7 (2.4–62.8) kg] over a 27-month (Oct 2011–Dec 2013) period. **Results:** Bench testing revealed that there was no stent shortening for dilatation to nominal diameter and beyond. The 5 mm stents could be dilated up to 10 mm, and the 10 mm stents to 20 mm. Stents were implanted through 4–7F sheaths or guide catheters over appropriate wires. Stent tracking and delivery was excellent. Twenty-three stents were implanted in the right ventricular outflow tract in Fallot-type lesions, 53 for branch pulmonary artery stenosis (22 post cavopulmonary shunt/Fontan), 14 conduit stenosis, 13 Fontan fenestrations, 3 PDA in hybrid stage I Norwood, 5 in coarctation, and 1 for SVC obstruction. Sixty-one stents (54%) were overdilated. There were no stent fractures. Radial strength was very good, whereas stent conformability was limited. **Conclusions:** The Cook Formula stent is a premounted balloon-expandable stent that can be significantly overdilated with virtually no shortening allowing for precise placement and minimal protrusion into adjacent vessels. The Formula stent is a very versatile addition to the range of stents for use in the catheter treatment of complex congenital heart disease in children. © 2014 Wiley Periodicals, Inc.

Key words: stent; congenital heart disease; Fontan procedure; tetralogy of Fallot

INTRODUCTION

Stents are increasingly being used in the treatment of congenital heart disease [1–7]. The preference is for balloon expandable stainless-steel stents, as they provide sufficient radial strength and allow for future further dilatations, to accommodate for somatic growth [4,8]. There are a wide variety of stents available [9], yet only few have been licensed for use in cardiac indications—thus, stents in the treatment of congenital heart disease are mostly used off-label [10].

The ideal stent for use in congenital heart disease patients should be premounted [11], deliverable through small sheaths, be flexible, redilatable to 15–18 mm maximum size, should have minimal shortening, and have good radial strength. Self-expanding stents cannot be over-dilated and thus do not fit the bill [12]. Coronary balloon-expandable stents are very flexible and can be introduced through 4F sheaths or 6F guide catheters, but cannot be expanded beyond 6 or 7 mm [13].

Thus, most pediatric cardiologists have looked at using stents initially designed for biliary or renal work. Such stents have nominal diameters of 5–10(12) mm and potentially can be dilated further [14–17]. Ex vivo

bench testing, in particular to look at shortening characteristics of these stents during over dilation has been pioneered by Ing and Stern [2,16].

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The Heart Unit, Birmingham Children's Hospital, Birmingham, United Kingdom

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*Correspondence to: Dr O Stumper, Heart Unit, Children's Hospital, Steelhouse Lane, Birmingham B4 6NH, UK.
E-mail: oliver.stumper@bch.nhs.uk

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The Cook Formula stent family is a relatively recent hybrid cell design licensed for biliary, renal and peripheral vascular work. This report summarizes our experience with this stent in the treatment of children with a wide variety of congenital heart disease over a 27-month period between October 2011 and December 2013.

METHODS AND PATIENTS

Until mid 2011 the balloon expandable stent most commonly used in our institution for the treatment of pulmonary artery stenoses was the JoStent (Abbott Vascular, Abbott Park, IL). When production ceased at the end of 2010 we needed a replacement. Various designs and manufacturers were considered. Following local bench testing, the clinical consensus was to use the Cook Formula stent family in our pediatric cardiac practice.

Bench Testing

Bench testing was carried out with sample stent designs provided by various companies. Stents were inflated and expanded to their nominal diameter recommended by each stent manufacturer. Stents were then serially overdilated using a series of noncompliant balloons in sequential size increments of 2 mm. Shortening characteristics, stent integrity (e.g., strut design, fractures, etc.), as well as stent diameter and stent length were measured at each sequential stage of overdilation. Balloons used for overdilation (12–24 mm) were the Cordis Powerflex®, Cordis OPTA® (Johnson and Johnson, Cordis Corporation, Miami Lakes, FL) and the Bard ATLAS® PTA Dilatation Catheter (Bard Peripheral Vascular, Tempe, AZ). It was important to use short balloons to prevent “dog boning” of the stents.

Patients

All patients who underwent Cook formula stent implantation at our institution were included in this review. Between Oct 2011 and Dec 2013 112 Cook Formula stents were implanted in 97 patients with pre- or post-operative congenital heart disease. Median age at implantation was 3.9 years (range, 2 days–17.6 years) and median weight 13.7 (range, 2.4–62.8) kilogram. Fifty-two (54%) patients were male.

Procedures

All catheter procedures were carried out under general anaesthesia with endotracheal intubation. Intravenous Heparin (50iU/kg) was administered in all.

Complete hemodynamic and angiographic studies were carried out. Stents were implanted by Consultants or senior fellows in interventional cardiology. Routine antibiotic prophylaxis for implants was administered.

Stents were delivered through a 4 or 5 French Cook Flexor sheath or a 6 French Coronary guide catheter over a 0.014” wire, or over a 0.035” wire via a 7 F Mullins sheath. Since March 2013 we have been increasingly using the Cook 418 Formula stents, which are over the wire designs up to 8 mm nominal diameter. These can be delivered through 5 and 6F sheaths and the 8 mm stent can be overdilated to 17 mm.

Repeat angiography and hemodynamic assessment, together with cardiac ultrasound evaluation was carried out before sheath and wires were withdrawn and manual hemostasis was employed. All patients were commenced on Aspirin medication 3–5 mg/kg post procedure.

Indications

Thirty-eight patients had a univentricular and 59 patients a bi-ventricular circulation. The stents were placed for short ($n=24$), medium ($n=24$), or long-term indications ($n=64$), depending on the underlying lesion and the anticipated benefit. Twenty-two patients underwent stenting of the right ventricular outflow tract in the context of a Fallot-type lesions or stenting of the ductus arteriosus ($n=3$) in the setting of a hybrid procedure for Norwood stage I palliation (short-term). Twenty patients underwent stenting of a cardiac conduit, residual outflow obstruction or Fontan fenestration (medium-term and long-term). Fifty-two patients underwent stenting for (re-)coarctation, venous obstructions, or pulmonary artery stenosis in uni- or bi-ventricular circulations (long term). In 11 patients two stents were implanted during the same procedure (Fig. 3).

Outcome measures (e.g., improvement of oxygen saturations in RVOT stenting, increase of stented vessel diameter in pulmonary artery stenting, drop in oxygen saturation in Fontan fenestration stenting) were assessed and compared pre- and postintervention. Statistical analysis was performed using student's *t*-tests.

Follow-Up

All patients underwent clinical assessment and echocardiography on the day post procedure. Following hospital discharge all patients underwent detailed clinical follow-up including serial cardiac ultrasound studies, with the first review 2–6 weeks after the procedure and then based on clinical and echocardiographic findings. Repeat chest x-rays were only performed prior to

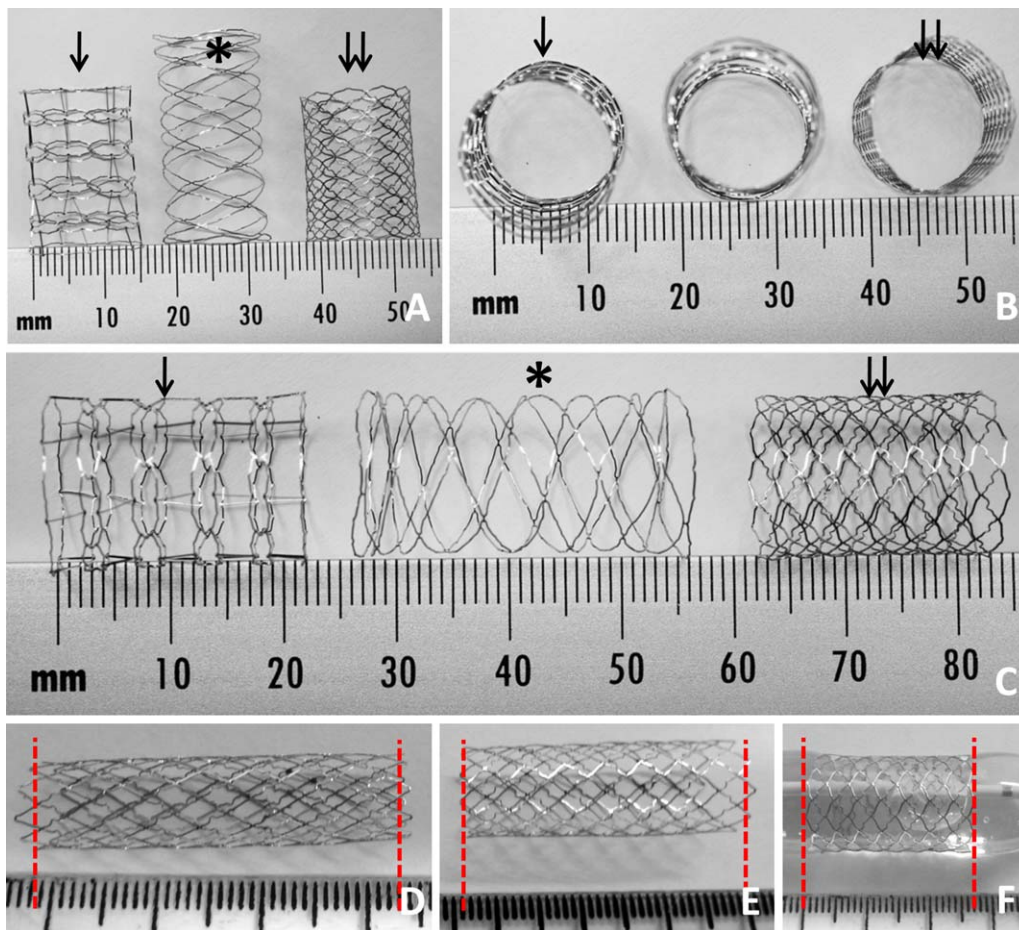


Fig. 1. A: Bench testing of a Cook formula® 418, 8 × 20 mm stent (single black arrow), a Bard Valeo® stent (*) 10 × 36 mm and Abbott Vascular® Jomed stent large (6–12 mm)–38 mm (double black arrow). Note the different stent and strut architecture. B: All three different stent types overdilated to 15 mm diameter. C: Illustrating no shorting of the Cook formula stent with integrity of its open/hybrid cell design. Note the different

cell design and its behaviour during over-dilation, especially for the Bard Valeo® stent. D–F: Illustrates significant shortening characteristics for the Abbott Vascular® Jomed large (6–12 mm)–38 mm during sequential dilation to nominal diameter (D), and further over-dilation (E and F). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

elective cardiac surgical intervention or incidental chest infections. Repeat cardiac catheterization or CT (computed tomography)/CMR (cardiac magnet resonance) imaging was only carried out on clinical grounds.

Ethical Approval

Stenting procedures in the treatment of congenital heart disease at our institution have been approved and used since 1992 with a variety of equipment. Individual stent designs are locally approved by the Drugs and Therapeutics committee. Ongoing analysis of the results of the use of stents in congenital heart disease is deemed mandatory as part of local clinical governance arrangements and thus the need for specific ethical approval for this study was waived. All patients and their parents gave their consent for on-going local

and national clinical audit of the results of cardiac catheter interventions.

RESULTS

Bench testing was carried out using sample stents provided by the different companies (examples of bench testing are illustrated in Fig. 1). The Cook Formula stent was tested further due to the nonshortening characteristics and the ability to over-dilate the stents significantly without a dramatic loss of radial strength. Sample stents were dilated to nominal diameter and the length was measured. Further bench dilatation was carried out using appropriate balloons, and achieved diameter and lengths were assessed (Fig. 2). The Cook Formula 414, 5, and 6 mm diameter stents were over-dilated to a maximum of 11–12 mm diameter, the

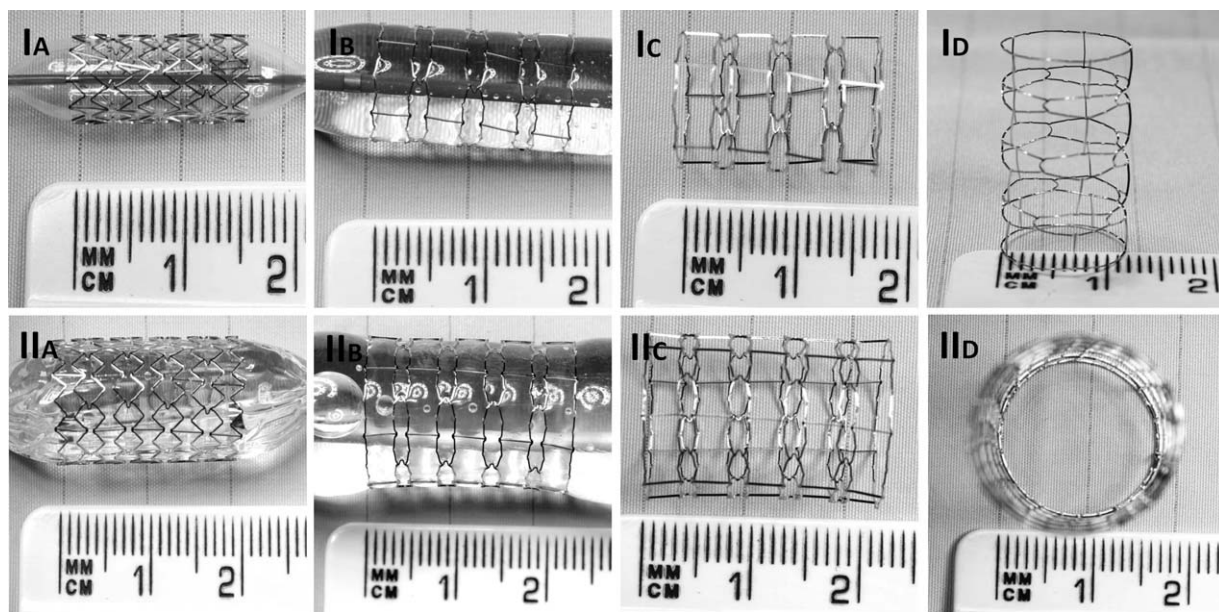


Fig. 2. Bench testing and overdilation of a Cook formula 414, 6 × 16 mm stent (top row) and a Cook formula 535, 10 × 20 mm stent (bottom row). Ia and IIa) Dilation to nominal diameter, Ib and IIb) Subsequent serial overdilation of the stents during bench testing, Ic and IIc) Stent length after overdilation to max. 12 mm (top row) and max. 18 mm (bottom row) show-

ing no stent shortening, Id and IId) Illustrates stent diameter overdilated to max. 12 mm for the Cook formula 414, 6 × 16 mm stent and max. 18 mm for the Cook formula 535, 10 × 20 mm stent with integrity of stent struts and stent architecture.

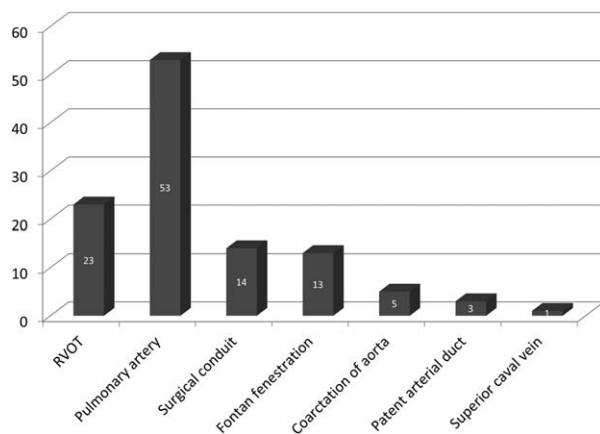


Fig. 3. Indications (x-axis) for 112 Cook Formula stents and number of stents (y-axis) implanted at different sites (x-axis). [RVOT, Right Ventricular Outflow Tract].

Cook Formula 418, 8 mm diameter up to 16 mm and the Cook Formula 535, 10 mm diameter up to maximal 20 mm. It was important to use short balloon lengths to achieve maximal diameter—ideally the same length or shorter than the actual stent [16].

A total of 112 Cook Formula stents were implanted in 97 patients over the 27 months observation period (Fig. 3). Thirteen patients underwent implantation of

two stents during the same procedure and two additional patients had a reintervention using a further Cook formula stent.

Median procedure time was 80 (18–222) min and median screening time was 23 (5–76) minutes. There were no procedural deaths. There were two balloon ruptures (both in patients with previously placed coronary stents) with fracture and embolization of the distal balloon tip in one, which was successfully retrieved. There were two stent embolizations, one in a patient undergoing RVOT stenting, one in a patient undergoing left pulmonary artery stenting—both stents were successfully retrieved using a large bore long sheath and a gooseneck snare. One of these patients had a further stent placed successfully positioned in the RVOT; in the other patient the procedure was abandoned.

Nineteen patients underwent stenting of the native right ventricular outflow tract for Fallot type lesions (additional three patients underwent stenting of the right ventricular outflow tract after previous RVOT stenting with a different stent type), at a median age of 4 months (2 days–11.9 years) and a median weight of 5.3 (2.9–24) kilogram. Stents used had a median diameter of 6(5–10) mm and a median length of 16 (12–20) mm. Systemic arterial saturations increased from 78 (66–93)% to 93 (89–98)% [$P < 0.001$].

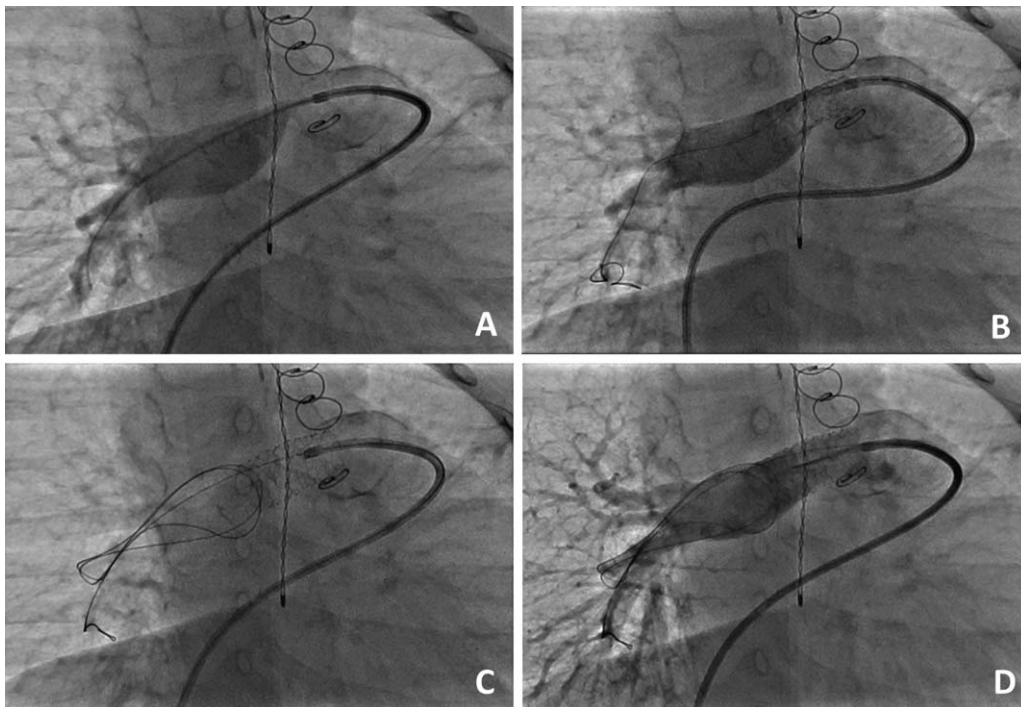


Fig. 4. Stenting of right pulmonary artery stenosis in a 3-year-old (13 kg) patient after complete repair of a common arterial trunk with a 15 m aortic homograft (RV/PA conduit). A: RPA origin stenosis, B: initial stenting with Cook formula 414, 7 × 20 mm stent. C: Overdilation of stent with 10 × 20 mm balloon with no stent shortening, D: Final result.

Forty-seven patients underwent stenting of branch pulmonary artery stenosis (bilateral in 4). Pre procedural minimal pulmonary artery diameter was a median of 4.75 (1.0–8.0) mm and increased post stenting to 10 (5.0–15.0) mm [$P < 0.001$].

Thirteen stents were used in 12 patients for stenting of a Fontan fenestration in the early postoperative period for low cardiac output, prolonged pleural effusions, or protein losing enteropathy. The most commonly used stent was a 5 × 16 mm (five patients) or 6 × 12 mm (three patients) Formula stent which was subsequently flared to 10 mm achieving a diabolo configuration. Saturations decreased from a median 95 (85–100)% to 88 (83–92)% [$P < 0.01$].

Thirteen patients underwent stenting of a right ventricular to pulmonary artery conduit. Eleven of these had a biventricular circulation and pressure gradients were reduced from a median of 48 (32–76) mm Hg to 15 (8–25) mm Hg [$P < 0.001$].

Nine stents were implanted for miscellaneous lesions such as (re-)coarctation (five patients, two with univentricular circulation), obstruction of the superior vena cava ($n = 1$), or for maintaining ductal patency in a stage I Norwood hybrid procedure ($n = 3$). One patient with coarctation stenting had Alagille's syndrome and

one patient had Williams-Beuren syndrome, whereas one stent was implanted in a patient with recoarctation and previous stenting of the CoA with a Jomed stent.

Sixty-one stents (54%) placed were primarily overdilated by a median of 2 (1–6) mm resulting in a median increase of 25 (14–100)% above nominal diameter (Fig. 4). A total of 10 stents (9%) were further dilated during the follow-up period by a median of 2 (1–4) mm.

All patients underwent serial clinical assessments and echocardiography during follow-up. Length of clinical follow-up time was median 220 days (range, 12–762 days) for all stents. On clinical grounds there was no suspicion of stent fractures or stent occlusions over the observation period. Further imaging (including chest x-rays or CT angio, CMR) were only performed based on other clinical indications, not to check stent conformation alone. Overall 91/112 stents (81%) were visualized with other imaging modalities during follow-up. Eighteen stents (16%) were visualized during repeat cardiac catheterization, 62 stents (55%) on chest x-rays (median 61 days post procedure) and a further 16 (14%) were visualized on CT angio/MRI (see also Table I). There were no stent fractures or stent occlusions noted on further imaging during the follow-up period.

TABLE I. Further Imaging of Implanted Cook Formula® Stents During Follow-Up Period

Indication	Total number	Primarily overdilated	Removed (surgery)	Stent duration until removal	Length of follow-up	Total number of stents with further imaging	Stents seen on cardiac catheter	Reintervention	Stents seen on x-ray	Time to x-ray	Stents seen on CT	Time to CT
RVOT	23	6/23 (26%)	14 (61%)	138 d (13–462)	153 d (12–762)	21/23 (91%)	4/23 (17%)	4/23 (17%)	14 (61%)	88 d (1–785)	3	293 d (262–347)
Pulmonary artery	53	34/53 (64%)	6 (11%)	225 d (37–336)	232 d (36–680)	43/53 (81%)	3/53 (6%)	3/53 (6%)	30 (57%)	33 d (1–480)	10	86 d (7–385)
Superior caval vein	1	1/1 (100%)	–	–	325 d	1/1 (100%)	1/1 (100%)	1/1 (100%)	–	–	–	–
Coarctation of aorta	5	2/5 (40%)	–	–	101 d (87–362)	2/5 (40%)	1/5 (20%)	1/5 (20%)	1 (20%)	83 d	1	267 d
Fontan fenestration	13	7/13 (54%)	–	–	384 d (36–584)	13/13 (100%)	5/13 (38%)	5/13 (38%)	10 (77%)	63 d (24–287)	–	–
Surgical conduits	14	11/14 (79%)	2	306 d (116–496)	128 d (44–659)	8/14 (57%)	2/14 (14%)	2/14 (14%)	5 (36%)	115 d (1–509)	1	486 d
Patent arterial duct	3	1/3 (33%)	3 (100%)	125 d (120–129)	124 d (119–128)	3/3 (100%)	2/3 (66%)	2/3 (66%)	2 (66%)	57 d (2–111)	1	35 d
Total	112	62 (55%)	25 (22%)	142 d (13–496)	220 d (12–762)	91 (81%)	18 (16%)	18 (16%)	62 (55%)	61 d (1–785)	16 (14%)	180 d (7–486)

Illustrated are numbers of stents with further imaging and percentages, median time to imaging and its range during follow-up. (CT, computed tomography; CMR, cardiac magnet resonance; RVOT, right ventricular outflow tract).

The observation period for all stents was shortest for the RVOT and PDA stents, as these stents were implanted for short-term palliation only. Two RVOT stents were surgically removed after 12 and 23 days during complete repair of Fallot. Overall 25/112 stents (22%) were removed at the time of further surgery.

DISCUSSION

After the initial work by Mullins and colleagues [5,7] stents have become an integral part in the treatment of congenital heart disease. In growing patients it is important that stents can be further dilated over time—certainly in cases where no further intervention is planned. Self-expanding stents are therefore obsolete in most cases or indications. Stainless steel stents offer sufficient radial strength for most congenital applications. Premounted stents are convenient to use and reduce procedure time and normally can be delivered through smaller sheaths [11].

Stents with a closed cell design shorten with further dilatation. Over the years many operators and centers got accustomed to this and learned to accommodate for this stent behavior during initial stent selection and placement. During initial or subsequent overdilatation there was marked shortening of the stent ranging from 18 to 50% [13,18,19]. Interestingly, no reports are available to detail the effect such shortening has on the neo-intima covering the stent after implantation. The latest design in stents is the open cell or hybrid architecture, which holds promise of significant overdilatation without marked shortening. This should limit the intimal damage during later progressive dilatation.

The Cook Formula stent is one of the new generation hybrid open-cell design stainless steel stents. These stents are currently only licensed for noncardiac interventions. In Europe there has been a long established practice to consider the use of devices on an off-label basis for cardiac interventions under local clinical governance scrutiny, given that these devices are considered safe for use in other parts of the body or the circulation and are approved for human use by the international legislating bodies. For many years, we, and many other institutions, have used stents approved for biliary and renal interventions in cardiac applications with good effect.

Nonetheless, the quest for the ideal stent for the treatment of cardiovascular lesions in the growing child is still a matter of clinical urgency.

The median age and weight of patients in our series is relatively low compared with many published series of stents in congenital heart disease. The ability to deliver the stent through sheath sizes between 4 and 7F

is attractive, especially in younger children and infants. The Cook Formula stent is a premounted system, which comes as a monorail design (414) or as an over-the-wire design (418 and 535) [20]. This saves valuable time and reduces complications in complex procedures. Twenty-two patients in our cohort (23%) underwent stenting of the RVOT in the setting of Tetralogy of Fallot type lesions [21]. These infants are often fragile and unstable during the procedure and hence a smooth and rapid stent deployment is necessary. A premounted stent saves time and minimizes the risk of stent dislodgement during delivery.

The full range of Cook Formula stents were used for different indications and in the settings of single or biventricular circulations. This series documents that this is a versatile stent family, which can be used for indications ranging from ductal stenting in a neonate to coarctation stenting in a teenager. The immediate results and complication rate are comparable with previous published series in the literature using different stent designs in patients with congenital heart disease [16,17].

The ex vivo testing showed that the Cook formula stent is remarkably strong and shortens only minimally even with overdilatation up to 100% of its nominal diameter. In comparison, closed cell design stents can shorten from 18 to 50% depending on the degree of overdilatation [22]. The shortening in open cell design is less but with this family of stents we found virtually no shortening even with over dilatation up to 100%. This is a very important feature for any stent implantation, but especially in small infants where margin for error is small. The radial strength of this stent is excellent and we have not seen any stent fractures at nominal stent diameter or beyond. During bench testing we were able to crack a 10 mm stent with a 20 mm balloon at 14+ atmosphere pressure—again without shortening.

It is important to choose an initial size that allows for future dilatation to a size likely to be required in the medium to long term. In lesions where dilatation beyond 16 mm is required in future, one has to be cautious in choosing these stents below 7 mm initial diameter.

LIMITATIONS

A significant proportion of our patients had stents implantation for short to midterm indications. These stents were removed at the time of subsequent planned surgery. We did not obtain routine serial follow-up chest x-rays/fluoroscopy to look for stent fractures, but 81% of the stents were seen on further imaging other than echocardiography and no issues were encountered.

CONCLUSIONS

The presented case series indicates that the Cook Formula stent family is a valuable addition to the stenting of common congenital cardiac lesions. Appropriate licensing for this indication would allow for greater use of this stent design for congenital cardiac indications.

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